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10/582,948

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Francis Maes

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25269

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09/15/2011

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EXAMINER

MELLER, MICHAEL V

ART UNIT

PAPER NUMBER

1655

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/582,948	<b>Applicant(s)</b> MAES ET AL.	
	<b>Examiner</b> MICHAEL MELLER	<b>Art Unit</b> 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 5) ☒ Claim(s) 1-30 is/are pending in the application.
- 5a) Of the above claim(s) 18-30 is/are withdrawn from consideration.
- 6) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 7) ☒ Claim(s) 1-17 is/are rejected.
- 8) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 9) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/1/07, 7/13/11</u> . | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of Group I, claims 1-18, ethyl acetate for claims 4 and 9, water based alcohols for claim 10, and claims 16 and 17 in the replies filed on 10/15/2010 and 7/13/2011 are acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The election of species with regard to claims 4 and 9 is dropped.

Thus, claims 18-30 are withdrawn from further consideration on the merits by the examiner since they are drawn to non-elected subject matter.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 03/014287 (US 2005/0042318-Erdelmeier et al. is the English language equivalent) in view of applicant's admission on page 7 in the specification of the prior art, see page 7, lines 5-12 or JP 75010399 and further in view of Moll et al. (US 4160787).

Erdelmeier teaches that a hops extract is produced by an isomerization reaction (since isoxanthohumol is formed which can only happen via an isomerization reaction-see the examples), extracting with water, see abstract, paragraphs 6, 9-33, 38-47, the claims. Note that supercritical CO<sub>2</sub> is used before the extraction with water (clearly a residue is formed containing the extract-see paragraph 23, see paragraphs 22-26, and note that the extraction with water can happen more than once (paragraph 24), note that xanthohumol is in the extract resulting from the process of Erdelmeier (see paragraph 33), and note that the extract constitutes a mixture, note that least 3 % xanthohumol is yielded, and at least 0.5 % of 8-prenylnaringenin is yielded, see the claims, note that water based alcohols (aqueous ethanol) is used to extract the hops (see paragraph 25 and 32), note that the temperature is 60 degrees celsius (paragraph 31), note the process takes one or more hours (paragraph 31), note that a xanthohumol/8-prenylnaringenin ratio of at least 10 is achieved , see the examples.

Erdelmeier does explicitly state that KOH is used (note that claim 1 does not require any amount of base, thus it reads on zero amount of base), the limitations in claim 8, that the isomerization reaction is carried out in inert atmosphere, or that the hop extract is mixed with 8-alkylnaringenin or 8-isopentylnaringenin.

Applicant states at page 7 of the instant specification that, " It is remarked that in the known art, isomerisation of chalcones into their corresponding flavanones is usually carried out in a 5% ethanolic potassium hydroxide (e.g., Hansel and Schulz, 1988) under reflux conditions for 30 minutes, giving, a  $(8\text{-PN} \times 100\%) / (8\text{-PN} + 6\text{-PN})$  ratio of 40-46%. With the present invention however, the enrichment of the thermodynamically less stable 8-PN could be significantly increased, by carrying out the isomerisation reaction in water, in particular at ambient temperature."

JP teaches that hops are subjected to an isomerization reaction in the presence of KOH, see abstract.

Moll teaches that isomerization reactions involving hops are known to be done in inert atmospheres, see claim 6.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use KOH of at least 0.1 w/v % since applicants themselves make

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it clear that KOH (potassium hydroxide) is known in the art to be used for isomerization reactions, see page 7 of the instant specification. JP teaches that hops are subjected to an isomerization reaction in the presence of KOH at a 0.02-0.02 N aqueous alkali KOH solution. Thus, making it clear that it would have been obvious for one of ordinary skill in the art use KOH in the isomerization reaction of Erdelmeier since JP makes it clear that when hops are subjected to isomerization reactions, KOH is well known to be used. It further would have been obvious to use 0.1 w/v % of KOH since 0.1 w/v % is very low and can read on very small amounts of KOH which JP clearly at least has and applicant's admission clearly indicates that at least amounts as small as 0.1 w/v % would be obvious to use to yield a successful isomerization reaction.

It would also have been obvious to use an inert atmosphere during the isomerization process of hops in Erdelmeier since Moll makes it clear that hops are in an inert atmosphere when being subjected to an isomerization reaction.

Claim 8 is met since it does not further limit claim 1 since it makes no sense and has no written description. Since claim 8 cannot be understood since the ratio makes no sense, then it further limits claim 1 and is properly rejected.

Claims 15-17 fail to further limit claim 1 since 8-alkylnaringenin and 8-isopentylnaringenin are not known in the art, thus they fail to further limit claim 1. Both terms are not known in the art, thus they cannot further limit claim 1.

Note that claim 2 fails to further limit claim 1.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 2, 4-12, 14-17 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 03/014287 (US 2005/0042318-Erdelmeier et al. is the English language equivalent).

Erdelmeier teaches that a hops extract is produced by an isomerization reaction (since isoxanthohumol is formed which can only happen via an isomerization

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reaction-see the examples), extracting with water, see abstract, paragraphs 6, 9-33, 38-47, the claims. Note that supercritical CO<sub>2</sub> is used before the extraction with water (clearly a residue is formed containing the extract-see paragraph 23, see paragraphs 22-26, and note that the extraction with water can happen more than once (paragraph 24), note that xanthohumol is in the extract resulting from the process of Erdelmeier (see paragraph 33), and note that the extract constitutes a mixture, note that least 3 % xanthohumol is yielded, and at least 0.5 % of 8-prenylnaringenin is yielded, see the claims, note that water based alcohols (aqueous ethanol) is used to extract the hops (see paragraph 25 and 32), note that the temperature is 60 degrees celsius (paragraph 31), note the process takes one or more hours (paragraph 31), note that a xanthohumol/8-prenylnaringenin ratio of at least 10 is achieved , see the examples. Note that claim 1 does not require any amount of base, thus it reads on zero amount of base.

6. Claims 1, 2, 10, 11, 14, are rejected under 35 U.S.C. 102 (b) as being anticipated by JP 75010399.

JP teaches that hops is subjected to an isomerization reaction in the presence of aqueous KOH and boiled for 20-70 minutes, see abstract.



***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 8, 15-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

3. The claims are drawn to a hops extract which contains 8- prenylnaringenin and 6-prenylnaringenin, in a ratio of  $(8\text{- prenylnaringenin} \times 100\%) / (8\text{-prenylnaringenin} + 6\text{- prenylnaringenin})$  of at least 50% and an amount of a hop extract enriched in 8-alkylnaringenin wherein the 8-alkylnaringenin is 8-isopentylnaringenin.

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4. Thus, the claims are drawn to a hops extract which is claimed in a very ambiguous way. Are the amounts supposed to be percentages or what ? It is not clear what units 8-prenylnaringenin and 6-prenylnaringenin are supposed to be in for the ratio to work. Is one to use percentages of the compounds to figure out the ratio or amounts in grams ? If one uses percentages then why would one multiply by 100 %. Also, claim 20 states that the weight ratio of xanthohumol to 8-prenylnaringenin being at least 10. Does this mean a ratio of 10:1 xanthohumol to 8-prenylnaringenin ? Further the terms 8-alkylnaringenin and 8-isopentylnaringenin are not known in the art, thus they do not find written description from the instant application.

5. To provide adequate written description and evidence of possession of a claimed invention, the specification must provide sufficient distinguishing identifying characteristics of the invention. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In the instant case, the only factor present in the claims is drawn to a hops extract comprising a mixture of 8- prenylnaringenin and 6- prenylnaringenin, wherein the ratio of  $(8\text{- prenylnaringenin} \times 100\%) / (8\text{- prenylnaringenin} + 6\text{-prenylnaringenin})$  is at least 50% and that the extract has a weight ratio of xanthohumol to 8-prenylnaringenin being at least 10. The specification only ever refers to the above ratio and no further explanation of it is ever given. The specification

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gives no other terms other than 8-alkylnaringenin and 8-isopentylnaringenin which are not known in the art, thus they do not find written description from the instant application.

6. Accordingly, in the absence of sufficient recitation of distinguishing characteristics, the specification does not provide adequate written description of the claimed hops extract.

7. Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed (See page 1117). The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is now is claimed.” (See Vas-Cath at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of inhibitors, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation or identification. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See Fiers v. Revel, 25USPQ2d 1601 at 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18USPQ2d 1016.

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8. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

9. Therefore, the claimed hops extract does not meet the written description provision of 35 U.S.C. 112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 2, 8, 15-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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12. The claims claim a hops extract containing 8- prenylnaringenin and 6- prenylnaringenin, in a ratio of  $(8\text{- prenylnaringenin} \times 100\%) / (8\text{-prenylnaringenin} + 6\text{- prenylnaringenin})$  of at least 50%. Thus, the claims are drawn to a hops extract which is claimed in a very ambiguous way. Are the amounts supposed to be percentages or what ? It is not clear what units 8-prenylnaringenin and 6-prenylnaringenin are supposed to be in for the ratio to work. Is one to use percentages of the compounds to figure out the ratio or amounts in grams ? If one uses percentages then why would one multiply by 100 %. Also, claim 20 states that the weight ratio of xanthohumol to 8- prenylnaringenin being at least 10. Does this mean a ratio of 10:1 xanthohumol to 8- prenylnaringenin ? Further the terms 8-alkylnaringenin and 8-isopentylnaringenin are not known in the art, thus they are vague and indefinite since they have no art recognized meaning. Thus, these terms do not further limit claim 1.

In claim 2, water is again stated as the solvent which is redundant since water is claimed as the solvent in claim 1.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL MELLER whose telephone number is (571)272-0967. The examiner can normally be reached on Monday thru Thursday: 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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